UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

SW

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,622	12/12/2001	Paul F. Laeseke	960296.98636	5043

27114 7590 04/15/2004

QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE, SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER	
MARMOR II, CHARLES ALAN	
ART UNIT	**PAPER NUMBER**
3736	14

DATE MAILED: 04/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,622	LAESEKE ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- Th MAILING DATE of this communication appears on the cov r sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2003 and 01 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-8 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed October 17, 2003 and the RCE filed March 1, 2004. The Examiner acknowledges the amendments to the Specification; the amendments to claims 5 and 10; and the withdrawal of claims 1-4, 9 and 11-20. Claims 5-8 and 10 are currently pending.

Drawings

2. The replacement drawing sheet 2/2 was received on October 17, 2003. These drawings are approved by the Examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood ('007) in view of Moorman et al. ('033).

Wood teaches a biopsy apparatus with radio frequency cauterization and methods for its use. The apparatus is a biopsy needle assembly including an introducer shaft **18** that is a hollow, electrically conductive tube. The introducer shaft is covered by an outer insulating covering **20** such that an exposed first end of the shaft forms an electrically conductive surface **32** that

extends continuously between 1mm and 5cm, preferably 2cm, as measured along the insertion path. A biopsy needle **38** including a sampling means **52** is fit in the introducer shaft to be guided thereby. The biopsy needle **38** is supported by the introducer shaft. The cauterization electrode **32** may be a monopolar electrode and require use of large ground electrode pads (paragraph [0053]) that complete the circuit through a RF electrical source. In operation, the introducer shaft is inserted percutaneously into a patient along an insertion path to locate the conductive surface at or in proximity to a biopsy site; the biopsy needle is guided with the introducer shaft to the biopsy shaft to obtain a tissue sample; the biopsy sample is removed from the patient; and a cauterizing electrical power source is connected to the electrically conductive surface as the introducer shaft is withdrawn to cauterize tissue along the insertion path. Wood teaches all of the limitations of the claims except that a conductive stylet is supported by the introducer shaft.

Moorman et al. teaches a modular biopsy and track coagulation needle apparatus. The apparatus includes an introducer shaft **10** that is a hollow, electrically conductive tube. The introducer shaft **10** is a hollow tube that may be formed of a nonconductive hollow tube or of a conductive hollow tube that is covered by an outer insulating covering **17** such that an exposed first end of the shaft forms an electrically conductive surface. A biopsy needle **30** including a sampling means is fit in the introducer shaft to be guided thereby (Fig. 7). After a biopsy sample is taken using the biopsy needle **30**, the biopsy needle is withdrawn and a conductive stylet **35** is inserted into the introducer shaft. The stylet has a blunt distal end (col. 11, lines 48-50) forming a monopolar electrode **41** and is supported by the introducer shaft. The shaft portion of the conductive stylet includes a center conductor **55** surrounded by an outer insulating covering **60** in

order to provide an insulated conductor. The conductive stylet is used as the modular needle apparatus is withdrawn from the patient in order to cauterize and coagulate the biopsy track in order to prevent tumor seeding, hemorrhage and bile leakage (col. 12, lines 12-48).

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to withdraw a biopsy needle from an introducer shaft similar to that of Wood after a biopsy sample is taken and to then insert a conductive stylet into the introducer shaft in view of the teachings of Moorman et al. in order to cauterize and coagulate the biopsy track as the introducer shaft is withdrawn from the patient, so as to prevent tumor seeding, hemorrhage and bile leakage.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wood ('007) in view of Moorman et al. ('033) as applied to claim 5 above, and further in view of Ouchi ('221). Wood, as modified by Moorman et al. hereinabove, teaches all of the limitations of the claim except that the stylet has a rounded tip. Ouchi teaches an electrocautery stylet **12** that has a hemispherical tip (figure 7). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a stylet having a rounded tip with an introducer shaft similar to that of Wood, as modified by Moorman et al., in light of the teachings of Ouchi in order to prevent unnecessary damage to the tissue and bleeding.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wood ('007) in view of Lennox ('137).

Wood teaches a biopsy apparatus with radio frequency cauterization and methods for its use. The apparatus is a biopsy needle assembly including an introducer shaft **18** that is a hollow, electrically conductive tube. The introducer shaft is covered by an outer insulating covering **20** such that an exposed first end of the shaft forms an electrically conductive surface **32** that extends continuously between 1mm and 5cm, preferably 2cm, as measured along the insertion path. A biopsy needle **38** including a sampling means **52** is fit in the introducer shaft to be guided thereby. The biopsy needle **38** is supported by the introducer shaft. The cauterization electrode **32** may be a monopolar electrode and require use of large ground electrode pads (paragraph [0053]) that complete the circuit through a RF electrical source. In operation, the introducer shaft is inserted percutaneously into a patient along an insertion path to locate the conductive surface at or in proximity to a biopsy site; the biopsy needle is guided with the introducer shaft to the biopsy shaft to obtain a tissue sample; the biopsy sample is removed from the patient; and a cauterizing electrical power source is connected to the electrically conductive surface as the introducer shaft is withdrawn to cauterize tissue along the insertion path. Wood teaches all of the limitations of the claims except that a temperature sensor is positioned at the electrically conductive surface.

Lennox teaches that it is desirable to provide medical devices for RF coagulation and cauterization with a temperature sensor **29** disposed at the electrically conductive surface **28** in order to provide an indirect means of measuring and controlling the temperature of the tissue surrounding the electrode, so as to prevent excessive tissue damage.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide an electrically conductive surface on an assembly similar to that

of Wood with a temperature sensor in light of the teachings of Lennox in order to provide an indirect means of measuring and controlling the temperature of the tissue surrounding the electrically conductive surface, so as to prevent excessive tissue damage.

Response to Arguments

7. Applicant's arguments with respect to claims 5-8 and 10 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that provisional application 60/330,298 to Wood does not teach or disclose a conductive stylet that may be supported by the introducer shaft to provide a conductor for cauterization or a temperature sensor to monitor tissue temperature during needle track cauterization as claimed in claims 5 and 10 as amended. This argument has been considered, but is moot in view of the new grounds of rejection citing Woods modified by Moorman et al. or Lennox set forth hereinabove.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
April 12, 2004